

PSJ2 Exh 133

ABC Diversion Control Program effective June 25, 2007

Steve Mays

**Senior Director - Corporate Security & Regulatory Affairs
AmerisourceBergen Corporation**

Copyright 2007 – AmerisourceBergen - Not to be duplicated in whole or in part without the express written permission of AmerisourceBergen Corporation

CONFIDENTIAL

HIGHLY CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER

ABC-MSAGC00000101

ABDCMDL00000101

Regulatory Responsibility

Title 21 of the Code of Federal Regulations:

1301.71(a) - "All applicants and registrants shall provide **effective controls** and procedures to **guard against** theft and **diversion** of controlled substances."

Distributor Response: Develop policy to

HOW?

Distributors usually implement policies that mirror the Code of Federal Regulations' requirements:

1301.72 - Physical Security Controls – vault / cage construction and alarm system requirements – No Problem

1304 – Records and Reports of Registrants – information, maintenance, and inventory requirements – No Problem

1305 – Orders For Schedule I & II Controlled Substances – ordering, filling, executing, and endorsing DEA Forms 222 – No Problem

1301.74 – Other Security Controls – make a **good faith** inquiry; report **suspicious** orders; report **significant** losses – gray area

Regulatory Responsibility

Title 21 of the Code of Federal Regulations:

1301.74(b) - "The registrant shall design and operate a system to **disclose** to the registrant **suspicious orders** of controlled substances. The registrant shall inform Field Diversion Office of the Administration in his area of suspicious orders **when discovered** by the registrant."

Regulatory Responsibility

- ▶ Reporting suspicious orders to DEA does NOT relieve the distributor of the responsibility to maintain effective controls to prevent diversion.
- ▶ DEA cannot / will not tell a distributor:
 - if an order is or is not legitimate; and/or
 - if the distributor should or should not ship an order
- ▶ Distributor must make a “business” decision whether or not to ship the order.

ABC's Diversion Control Program

- ▶ **“Know Your Customer” Due Diligence**
- ▶ **48-Hour Reporting**
- ▶ **Order Monitoring Program (OMP)**
- ▶ **Investigations**
- ▶ **Education and Training**

New Customer Due Diligence

- ▶ “Know Your Customer” Due Diligence investigations completed on all new Retail and Distributor Accounts.
 - Retail chain pharmacies are exempted.

- ▶ Included in New Account Setup Process
 - New Account Questionnaire (CSRA Form 590)
 - On-site visit includes photographs inside and out (or physical description of premises)

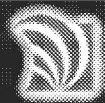
New Customer Due Diligence

► Monthly Sales Limits

- All new accounts set at the lowest threshold level for DEA business type in ABC's Order Monitoring Program (OMP)

► "Do Not Ship" List

- Customers to whom ABC has ceased distribution to due to suspicious activity
- Other sources



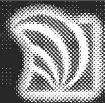
Order Monitoring Program (OMP)

- ▶ The Controlled Substances/Listed Chemicals Order Monitoring Program (OMP) was developed to identify suspicious orders and purchasing trends.
- ▶ Historically Controlled Substance / Listed Chemical order monitoring has been based on a **ship and report** process.
- ▶ ABC's OMP process is now based on: identify, capture, investigate, and report suspicious orders; all **prior to shipment**.

OMP Customer Account Type and Size

- ▶ Each Customer is classified by “Customer Type,” which represents how the customer is registered with DEA.
 - Hospital/Clinic, Retail Pharmacy, Distributor, etc.
 - This value is loaded using the NTIS Database synch process.

- ▶ Each customer is then categorized by “Customer Size” based upon average revenue relative to its peers in the same “Customer Type.”



OMP Item Family and Threshold

- ▶ All controlled substance and listed chemical products are grouped into item “families” based upon the drug’s active ingredient, which has a corresponding Generic Code Number (GCN).
- ▶ The OMP will combine all sales of items within the same GCN family (e.g., hydrocodone / vicodin; oxycodone / percocet; Alprazolam / Xanax), for each customer.

OMP Item Family and Threshold

- ▶ Item threshold levels are established from accumulated monthly sales for all customers based on item family, DEA type, and customer size.
- ▶ A customer's threshold level is initially set by item family based on the customer's DEA type and customer size.

OMP Order Processing

- ▶ A customer's incoming orders are accumulated by item family, and the total item family order quantity is applied to the predetermined Item family monthly threshold.
- ▶ If the order quantity falls below the Item family threshold, the order will process normally.

OMP Order Processing

- ▶ If the order quantity goes over the item family threshold, the order will be placed into “OMP Review.”
- ▶ All subsequent orders within the same item family will be rejected while an item within the same family is under review.
- ▶ Each distribution center (DC) is responsible for initial review of all orders in OMP Review.
 - If the DC can determine the order is not suspicious, the DC will release the order.
 - If the DC is unsure, the order will be flagged to be investigated by Corporate (CSRA).

OMP Order Processing

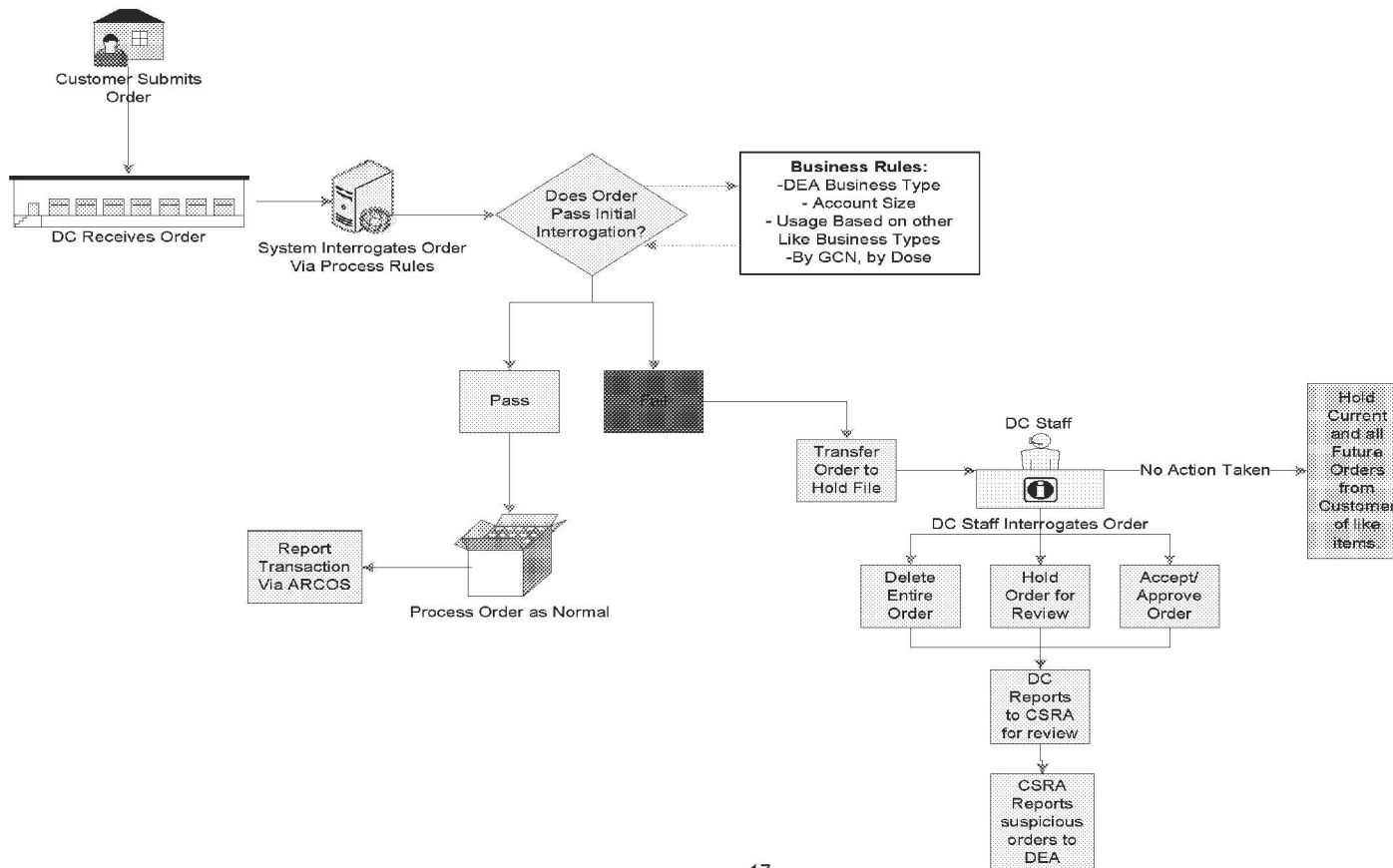
- ▶ All OMP orders that the DC released, as well as those flagged for CSRA Review, are sent to CSRA each morning.
- ▶ Based upon information available to CSRA, flagged orders will either be released or placed in “Investigate” status.
- ▶ All orders placed into Investigate status are electronically reported to DEA on a daily basis.

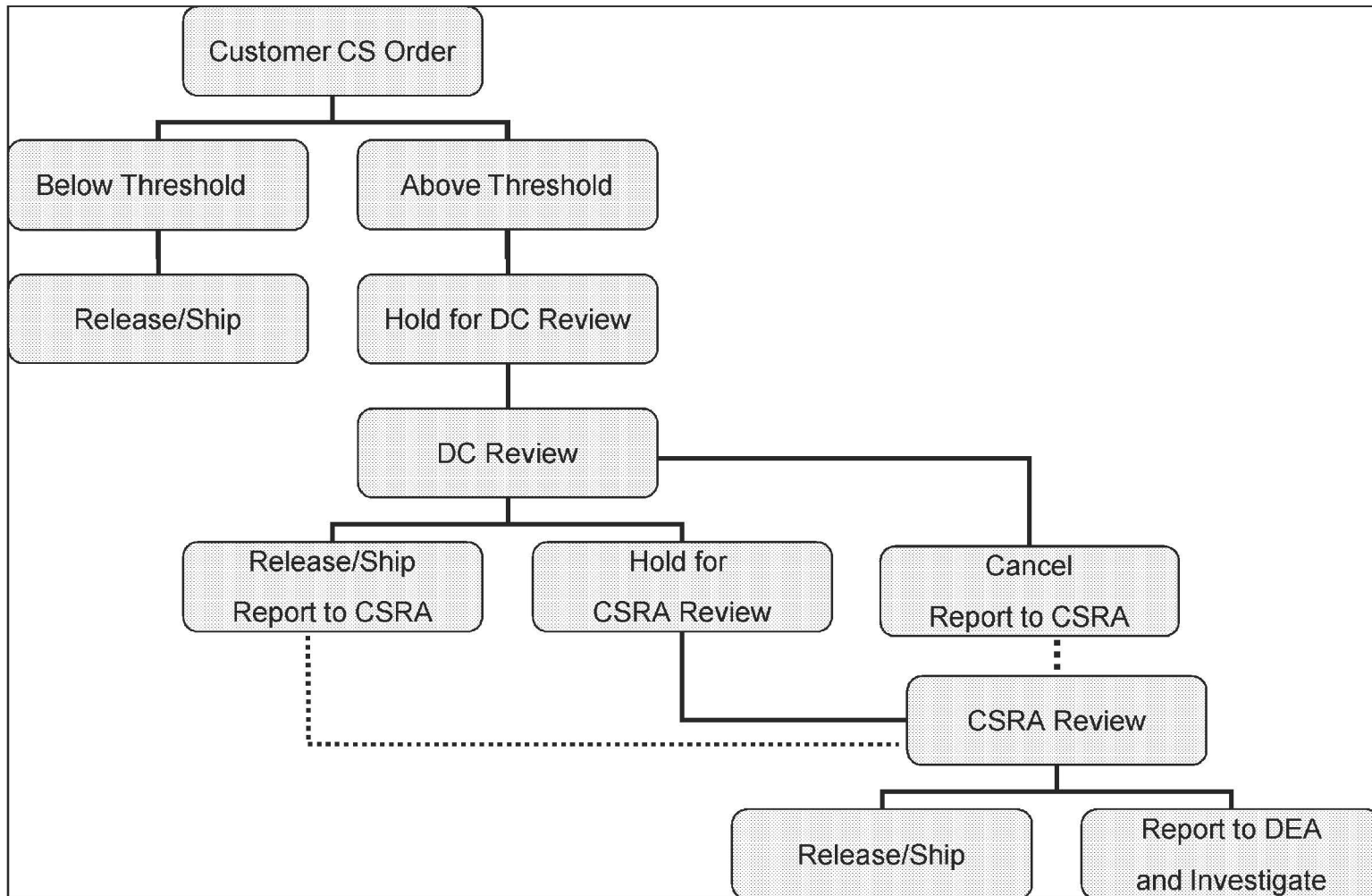
OMP Order Processing

- ▶ CSRA conducts the investigation and will notify the distribution center of the final disposition of the order (release or cancel).

- ▶ CSRA will also determine if any permanent action needs to be taken with the customer.
 - Customers who have legitimate needs will have their size or threshold levels increased.
 - Customers with continued suspicious ordering patterns may have their ability to order control substances effected.

Order Monitoring Process (OMP)





Order Monitoring Program (OMP)

- ▶ A Distributor can't solely rely on computer systems and programs to prevent diversion.
- ▶ All employees have a role and responsibility in a successful Order Monitoring Program:
 - Sales
 - Procurement
 - Management (DC / HQ)
 - Order fillers
 - Customer service
 - IT

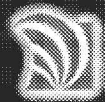
Investigations

- ▶ Sources of Investigations
 - Order Monitoring Program (OMP)
 - Monthly Customer Product Mix/Ratio Report
 - Notification by DEA
 - Notification by ABC DC Personnel
- ▶ Typical Investigation Process
 - One-year purchase history
 - On-site inspection
 - **CSRA Form 590 Pharmacy Questionnaire**
 - **CSRA Form 590c Retail Pharmacy Verification Checklist**
- ▶ Decision
 - Cease distribution of CS/LC to customer
 - Customer Sign applicable compliance agreement

Education and Training

- ▶ All appropriate associates are trained on ABC's Diversion Control Program
- ▶ ABC also holds training and educational courses for its customers and vendors regarding this subject matter.





Questions?